

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ICEUTICA PTY LTD and IROKO  
PHARMACEUTICALS, LLC,

Plaintiffs,

v.

APOTEX, INC., and APOTEX CORP.,

Defendants.

C.A. No. \_\_\_\_\_

**JURY TRIAL DEMANDED**

**COMPLAINT**

For their Complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively “Apotex”), Plaintiffs iCeutica Pty Ltd (“iCeutica”) and Iroko Pharmaceuticals, LLC (“Iroko”) (collectively, “Plaintiffs”), by their attorneys, allege as follow:

**NATURE OF ACTION**

1. This is an action for infringement of United States Patent Nos. 8,679,544 (“the ’544 patent”), 8,999,387 (“the ’387 patent”), 9,017,721 (“the ’721 patent”), 9,173,854 (“the ’854 patent”), 9,180,095 (“the ’095 patent”), 9,180,096 (“the ’096 patent”), and 9,186,328 (“the ’328 patent”) under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(e)(2), 271(a), 271(b), and 271(c), and for a declaratory judgment of infringement of the ’544, ’387, ’721, ’854, ’095, ’096, and ’328 patents under 28 U.S.C. §§ 2201 and 2202 relating to Plaintiffs’ commercially successful nonsteroidal anti-inflammatory drug, ZORVOLEX® (diclofenac) Capsules 18 mg and 35 mg.

### **THE PARTIES**

2. Plaintiff iCeutica Pty Ltd is a company organized and existing under the laws of Australia with a principal place of business at Unit 2, 32 Mumford Place, Balcatta Western Australia 6021.

3. Plaintiff Iroko Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at One Kew Place, 150 Rouse Boulevard, Philadelphia, PA, 19112.

4. Upon information and belief, Defendant Apotex, Inc. is a corporation organized under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. Upon information and belief, Defendant Apotex Corp. is a corporation organized under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Corp. is a subsidiary of Apotex Inc., and is controlled by Apotex Inc.

7. Upon information and belief, Apotex Corp. acts as the authorized U.S. agent of Apotex Inc. with respect to ANDA No. 210299, and it will work, either directly or indirectly, to manufacture, import, market, and sell the proposed generic Diclofenac capsules 18 mg and 35 mg.

8. Upon information and belief, Apotex Inc. is in the business of, among other things, developing, preparing, manufacturing, packaging, marketing, and selling generic versions of branded pharmaceutical products for the United States market, including in this judicial district and the State of Delaware, through its own systemic, continuous, constant and pervasive actions and through those of its agents and operating subsidiaries, including its subsidiary, Apotex Corp.

9. On information and belief, Apotex Inc. and Apotex Corp. have previously submitted to this Court's jurisdiction. *See, e.g., Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:07-cv-00779 D.I. 13 (D. Del. Jan. 22, 2008); *Forest Labs. Inc. et al. v. Apotex Corp. et al.*, Civil Action No. 1:14-cv-00200 D.I. 32 (D. Del. May 6, 2014). Upon information and belief, Apotex Inc. and Apotex Corp. have also availed themselves of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g., Apotex Inc. et al. v. Senju Pharm. Co., Ltd. et al.*, Civil Action No. 1:12-cv-00196 D.I. 1 (D. Del. Feb. 16, 2012); *Apotex Inc. et al. v. Pfizer Inc. et al.*, Civil Action No. 1:03-00990 D.I. 1 (D. Del. Oct. 29, 2003).

10. Apotex Inc. and Apotex Corp. have also purposefully availed themselves of the jurisdiction of this Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this District. *See, e.g., Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:07-cv-00779 D.I. 13 (D. Del. Jan. 22, 2008); *Forest Labs. Inc. et al. v. Apotex Corp. et al.*, Civil Action No. 1:14-cv-00200 D.I. 32 (D. Del. May 6, 2014).

11. Upon information and belief, Apotex Corp. and Apotex Inc. are working on concert to engage in the sale and distribution of generic versions of branded pharmaceutical products, including those manufactured by Apotex Inc., in the United States, including in this judicial district and the State of Delaware, through its own systematic, continuous, constant and pervasive actions and through those of its agents.

12. Upon information and belief, Apotex Corp. is a licensed drug manufacturer and wholesaler in Delaware.

### **JURISDICTION AND VENUE**

13. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.*, including §§ 271(e)(2), 271(a), 271(b), and 271(c), and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

14. This Court has personal jurisdiction over Apotex, Inc. by virtue of, *inter alia*, the fact that Apotex, Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Iroko Pharmaceuticals LLC, a Delaware company that conducts business in Delaware and derives substantial revenue therefrom and is a Delaware resident, and because Apotex, Inc. has engaged in purposeful systematic and continuous contacts with the State of Delaware. This Court has personal jurisdiction over Apotex, Inc. for the additional reasons set forth in this Complaint and for other reasons that will be presented to the Court if jurisdiction is challenged.

15. This Court has personal jurisdiction over Apotex, Inc. because, upon information and belief, Apotex, Inc. regularly does business in Delaware and has engaged in a persistent course of purposeful conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

16. This Court has personal jurisdiction over Apotex Inc. because, on information and belief, Apotex Inc., acting in concert with Apotex Corp., has engaged in conduct that reliably predicts Delaware activities by Apotex. On information and belief, Apotex Inc., by acting in concert with Apotex Corp. and submitting ANDA No. 210299, has taken the significant step of

applying to the FDA for approval to engage in future activities—including wrongful marketing of its generic drugs—that will be purposefully directed at Delaware.

17. This Court has personal jurisdiction over Apotex, Inc. because Apotex, Inc. has previously been sued in this district and has not challenged personal jurisdiction, and Apotex, Inc. has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:07-cv-00779 D.I. 13 (D. Del. Jan. 22, 2008); *Forest Labs. Inc. et al. v. Apotex Corp. et al.*, Civil Action No. 1:14-cv-00200 D.I. 32 (D. Del. May 6, 2014). Apotex Inc. has also availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g., Apotex Inc. et al. v. Senju Pharm. Co., Ltd. et al.*, Civil Action No. 1:12-cv-00196 D.I. 1 (D. Del. Feb. 16, 2012); *Apotex Inc. et al. v. Pfizer Inc. et al.*, Civil Action No. 1:03-00990 D.I. 1 (D. Del. Oct. 29, 2003).

18. This Court also has personal jurisdiction over Apotex, Inc. by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Delaware law, and has engaged in systematic, continuous, constant and pervasive contacts with the State.

19. This Court has personal jurisdiction over Apotex Corp. as it is incorporated in Delaware. As a domestic corporation, Apotex Corp. is registered to do business with the Delaware Department of State Division of Corporations. This Court also has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Iroko Pharmaceuticals LLC, a Delaware company that conducts business in Delaware and derives substantial revenue therefrom, and because Apotex Corp. has engaged in purposeful systematic and continuous contacts with the

State of Delaware. This Court has personal jurisdiction over Apotex Corp. for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

20. This Court has personal jurisdiction over Apotex Corp. because, upon information and belief, Apotex Corp. regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

21. This Court has personal jurisdiction over Apotex Corp. by virtue of, inter alia, the fact that Apotex Corp. distributes drug products for sale throughout the United States, including in this judicial district.

22. This Court has personal jurisdiction over Apotex Corp. because, on information and belief, Apotex Corp., acting in concert with Apotex Inc., has engaged in conduct that reliably predicts Delaware activities by Apotex. On information and belief, Apotex Corp., by acting in concert with Apotex Inc. and submitting ANDA No. 210299, has taken the significant step of applying to the FDA for approval to engage in future activities—including wrongful marketing of its generic drugs—that will be purposefully directed at Delaware.

23. The Court has personal jurisdiction over Apotex Corp. because Apotex Corp. has previously been sued in this district and has not challenged personal jurisdiction, and Apotex Corp. has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:07-cv-00779 D.I. 13 (D. Del. Jan. 22, 2008); *Forest Labs. Inc. et al. v. Apotex Corp. et al.*, Civil Action No. 1:14-cv-00200 D.I. 32 (D. Del. May 6, 2014). Apotex Corp. has also availed itself of the legal

protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g., Apotex Inc. et al. v. Senju Pharm. Co., Ltd. et al.*, Civil Action No. 1:12-cv-00196 D.I. 1 (D. Del. Feb. 16, 2012); *Apotex Inc. et al. v. Pfizer Inc. et al.*, Civil Action No. 1:03-00990 D.I. 1 (D. Del. Oct. 29, 2003).

24. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Delaware law, and has engaged in systematic, continuous, constant and pervasive contacts with the State.

25. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

### **FACTUAL BACKGROUND**

26. The '544 patent, entitled "Formulation of Diclofenac," issued on March 25, 2014 and names Aaron Dodd, Felix Meiser, Marck Norret, Adrian Russell, and H. William Bosch as inventors. A true and accurate copy of the '544 patent is attached hereto as Exhibit A.

27. The '387 patent, entitled "Formulation of Diclofenac," issued on April 7, 2015 and names Aaron Dodd, Felix Meiser, Marck Norret, Adrian Russell, and H. William Bosch as inventors. A true and accurate copy of the '387 patent is attached hereto as Exhibit B.

28. The '721 patent, entitled "Formulation of Diclofenac," issued on April 28, 2015 and names Aaron Dodd, Felix Meiser, Marck Norret, Adrian Russell, and H. William Bosch as inventors. A true and accurate copy of the '721 patent is attached hereto as Exhibit C.

29. The '854 patent, entitled "Formulation of Diclofenac," issued on November 3, 2015 and names Aaron Dodd, Felix Meiser, Marck Norret, Adrian Russell, and H. William Bosch as inventors. A true and accurate copy of the '854 patent is attached hereto as Exhibit D.

30. The '095 patent, entitled "Formulation of Diclofenac," issued on November 10, 2015 and names Aaron Dodd, Felix Meiser, Marck Norret, Adrian Russell, and H. William Bosch as inventors. A true and accurate copy of the '095 patent is attached hereto as Exhibit E.

31. The '096 patent, entitled "Formulation of Diclofenac," issued on November 10, 2015 and names Aaron Dodd, Felix Meiser, Marck Norret, Adrian Russell, and H. William Bosch as inventors. A true and accurate copy of the '854 patent is attached hereto as Exhibit F.

32. The '328 patent, entitled "Formulation of Diclofenac," issued on November 17, 2015 and names Aaron Dodd, Felix Meiser, Marck Norret, Adrian Russell, and H. William Bosch as inventors. A true and accurate copy of the '328 patent is attached hereto as Exhibit G.

33. iCeutica Pty Ltd, as assignee, owns the entire right, title and interest in the '544, '387, '721, '854, '095, '096, and '328 patents.

34. Iroko Pharmaceuticals, LLC is the exclusive licensee to the '544, '387, '721, '854, '095, '096, and '328 patents in the United States.

35. Iroko Pharmaceuticals, LLC is the holder of an approved New Drug Application ("NDA") No. 20-4592 for Diclofenac capsules 18 mg and 35 mg, sold under the ZORVOLEX® registered trademark.

36. In conjunction with that NDA, Iroko Pharmaceuticals, LLC has listed with the FDA the '544, '387, '721, '854, '095, '096, and '328 patents. The FDA has published the '544, '387, '721, '854, '095, '096, and '328 patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

37. ZORVOLEX® is covered by at least one claim of the '544, '387, '721, '854, '095, '096, and '328 patents.



38. On information and belief, Apotex became aware of the '544, '387, '721, '854, '095, '096, and '328 patents no later than when they were issued by the Patent Office and/or listed in the Orange Book as covering formulations and methods of using the approved formulation of ZORVOLEX®.

39. On or about September 21, 2017, Plaintiffs received a letter, dated September 20, 2017, signed on behalf of Apotex by Deepto R. Mukerjee ("Apotex's Paragraph IV Letter").

40. Apotex's Paragraph IV Letter stated that Apotex had submitted, and the FDA had received, an Abbreviated New Drug Application ("ANDA") under section 505(j)(2)(B)(ii) of the FDCA, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Diclofenac capsules 18 mg and 35 mg, a generic version of the ZORVOLEX® product, prior to expiration of the '544, '387, '721, '854, '095, '096, and '328 patents. The ANDA number for Apotex's application is 210299.

41. On information and belief, Apotex Corp. is the authorized representative for Apotex, Inc. concerning ANDA No. 210299.

42. Apotex's Paragraph IV Letter stated that the '544, '387, '721, '854, '095, '096, and '328 patents are invalid and/or would not be infringed by the commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

43. Attached to Apotex's Paragraph IV Letter was a statement of the factual and legal bases for Apotex's opinion that the '544, '387, '721, '854, '854, '095, '096, and '328 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

44. In filing its ANDA No. 210299, Apotex has requested the FDA's approval to market a generic version of the ZORVOLEX® product throughout the United States, including in this judicial district.

45. On information and belief, following FDA approval of ANDA No. 210299, Apotex will manufacture, sell, offer to sell, and/or import the approved generic version of the ZORVOLEX® product throughout the United States, including in this judicial district.

46. On information and belief, following FDA approval of ANDA No. 210299, Apotex Corp., as the marketing and sales agent for Apotex Inc., will sell and/or offer to sell the approved generic version of the ZORVOLEX® product manufactured by Apotex throughout the United States, including in this judicial district.

47. Since receiving Apotex's Paragraph IV Letter, and prior to the filing of the Initial Complaint, Plaintiffs attempted to procure a copy of ANDA No. 210299 from Apotex. Because the terms of the proposed offer would not allow Plaintiffs to meaningfully process the information contained in the ANDA Plaintiffs could not agree to the terms of the original offer. On October 14, 19, and 23, 2017, counsel for Plaintiffs sent Apotex's counsel letters in an attempt to negotiate Plaintiffs' access to ANDA 210299. As of the filing of the Initial Complaint, the parties could not reach acceptable terms for accessing the ANDA.

48. Plaintiffs are not aware of any other means for obtaining information regarding Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that Apotex's proposed Diclofenac capsules 18 mg

and 35 mg fall within the scope of one or more claims of the '544, '387, '721, '854, '095, '096, and/or '328 patents.

49. Because they have been unable to obtain a copy of ANDA 210299, Plaintiffs allege the causes herein based primarily on the representations contained in Apotex's Paragraph IV Letter and the other facts alleged herein.

### **COUNT I**

#### ***(Infringement of the '544 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

50. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

51. Apotex, Inc. submitted ANDA No. 210299 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Diclofenac capsules 18 mg and 35 mg throughout the United States. By submitting this application, Apotex, Inc. has committed an act of infringement of the '544 patent under 35 U.S.C. § 271(e)(2)(A).

52. On information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 210299. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 210299 constitutes an act of infringement of the '544 patent under 35 U.S.C. § 271(e)(2)(A).

53. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of direct infringement of the '544 patent.

54. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

55. Unless and until Apotex is enjoined from infringing the '544 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

## **COUNT II**

### ***(Declaratory Judgment of Infringement of the '544 Patent Under 35 U.S.C. § 271(a) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

56. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

57. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

58. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

59. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg immediately and imminently upon approval of ANDA No. 210299.

60. Apotex's actions, including but not limited to, the development of its proposed generic Diclofenac capsules 18 mg and 35 mg, the filing of an ANDA with a Paragraph IV certification, and, on information and belief, the manufacture of exhibit batches of its proposed generic Diclofenac capsules 18 mg and 35 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

61. On information and belief, Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

62. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of direct infringement of the '544 patent.

63. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

64. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration by Apotex will constitute direct infringement of the '544 patent.

65. Unless and until Apotex is enjoined from infringing the '544 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

### **COUNT III**

#### ***(Infringement of the '387 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

66. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

67. Apotex, Inc. submitted ANDA No. 210299 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Diclofenac capsules 18 mg and 35 mg throughout the United States. By submitting this application, Apotex, Inc. has committed an act of infringement of the '387 patent under 35 U.S.C. § 271(e)(2)(A).

68. On information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 210299. Apotex Corp.'s participation in,

contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 210299 constitutes an act of infringement of the '387 patent under 35 U.S.C. § 271(e)(2)(A).

69. On information and belief, Apotex will include within the packaging of its generic Diclofenac capsules 18 mg and 35 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in the '387 patent.

70. On information and belief, a patient's use of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg according to the instructions included in the label and/or instructions for use of those products will constitute an act of direct infringement of one or more of the methods claimed in the '387 patent.

71. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg are a material part of one or more of the methods claimed in the '387 patent.

72. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg have no substantial uses that do not constitute infringement of one or more of the methods claimed in the '387 patent.

73. On information and belief, Apotex became aware of the '387 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using the approved formulation of ZORVOLEX®.

74. On information and belief, upon awareness of the '387 patent, Apotex either actually knew of the potential for infringement of one or more claims of the '387 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to perform one or more methods claimed in the '387 patent.

75. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration will constitute an act of contributory infringement and/or active inducement of infringement of the '387 patent.

76. On information and belief, Apotex knew or should have known that its commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg will actively induce the actual infringement of the '387 patent.

77. On information and belief, Apotex knew or should have known that its proposed generic Diclofenac capsules 18 mg and 35 mg will be especially made or especially adapted for use in an infringement of the '387 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg will actively contribute to the actual infringement of the '387 patent.

78. The commercial manufacture, distribution, marketing, use, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

79. Unless and until Apotex is enjoined from infringing the '387 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

#### **COUNT IV**

***(Declaratory Judgment of Infringement of the '387 Patent Under 35 U.S.C. § 271(b) and/or 271(c) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

80. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

81. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

82. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

83. On information and belief, Apotex will engage in the commercial manufacture, distribution, use, offer for sale, sale and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg immediately and imminently upon approval of ANDA No. 210299.

84. Apotex's actions, including but not limited to, the development of its proposed generic Diclofenac capsules 18 mg and 35 mg, filing of an ANDA with Paragraph IV certifications, and, on information and belief, the manufacture of exhibit batches of its proposed generic Diclofenac capsules 18 mg and 35 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

85. On information and belief, Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, distribute, sell, offer to sell, and/or import Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

86. On information and belief, Apotex will include within the packaging of its generic Diclofenac capsules 18 mg and 35 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in the '387 patent.

87. On information and belief, a patient's use of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg according to the instructions included in the label and/or instructions



for use of those products will constitute an act of direct infringement of one or more of the methods claimed in the '387 patent.

88. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg are a material part of one or more of the methods claimed in the '387 patent.

89. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg have no substantial uses that do not constitute infringement of one or more of the methods claimed in the '387 patent.

90. On information and belief, Apotex became aware of the '387 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using the approved formulation of ZORVOLEX®.

91. On information and belief, upon awareness of the '387 patent, Apotex either actually knew of the potential for infringement of one or more claims of the '387 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to perform one or more methods claimed in the '387 patent.

92. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration will constitute an act of contributory infringement and/or active inducement of infringement of the '387 patent.

93. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

94. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, distribution, marketing, offer for sale, sale, and/or importation of Apotex's

proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration by Apotex will constitute contributory infringement and/or active inducement of infringement of the '387 patent.

95. Unless and until Apotex is enjoined from infringing the '387 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

### **COUNT V**

#### ***(Infringement of the '721 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

96. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

97. Apotex, Inc. submitted ANDA No. 210299 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Diclofenac capsules 18 mg and 35 mg throughout the United States. By submitting this application, Apotex, Inc. has committed an act of infringement of the '721 patent under 35 U.S.C. § 271(e)(2)(A).

98. On information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 210299. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 210299 constitutes an act of infringement of the '721 patent under 35 U.S.C. § 271(e)(2)(A).

99. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of direct infringement of the '721 patent.

100. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

101. Unless and until Apotex is enjoined from infringing the '721 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

**COUNT VI**

***(Declaratory Judgment of Infringement of the '721 Patent Under 35 U.S.C. § 271(a) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

102. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

103. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

104. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

105. [A] On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg immediately and imminently upon approval of ANDA No. 210299.

106. Apotex's actions, including but not limited to, the development of its proposed generic Diclofenac capsules 18 mg and 35 mg, the filing of an ANDA with Paragraph IV certifications, and, on information and belief, the manufacture of exhibit batches of its proposed generic Diclofenac capsules 18 mg and 35 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

107. On information and belief, Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

108. Any commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg prior to patent expiry will constitute direct infringement of the '721 patent.

109. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

110. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration by Apotex will constitute direct infringement of the '721 patent.

111. Unless and until Apotex is enjoined from infringing the '721 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

## **COUNT VII**

### ***(Infringement of the '854 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

112. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

113. Apotex, Inc. submitted ANDA No. 210299 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Diclofenac capsules 18 mg and 35 mg throughout the United States. By submitting this application, Apotex, Inc. has committed an act of infringement of the '854 patent under 35 U.S.C. § 271(e)(2)(A).

114. On information and belief, Apotex, Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 210299. Apotex Corp.'s participation in,

contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 210299 constitutes an act of infringement of the '854 patent under 35 U.S.C. § 271(e)(2)(A).

115. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of direct infringement of the '854 patent.

116. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

117. Unless and until Apotex is enjoined from infringing the '854 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

### **COUNT VIII**

#### ***(Declaratory Judgment of Infringement of the '854 Patent Under 35 U.S.C. § 271(a) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

118. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

119. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

120. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

121. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg immediately and imminently upon approval of ANDA No. 210299.

122. Apotex's actions, including but not limited to, the development of its proposed generic Diclofenac capsules 18 mg and 35 mg, the filing of an ANDA with Paragraph IV

certifications, and, on information and belief, the manufacture of exhibit batches of its proposed generic Diclofenac capsules 18 mg and 35 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

123. On information and belief, Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

124. Any commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg prior to patent expiry will constitute direct infringement of the '854 patent.

125. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

126. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration by Apotex will constitute direct infringement of the '854 patent.

127. Unless and until Apotex is enjoined from infringing the '854 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

### **COUNT IX**

#### ***(Infringement of the '095 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

128. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

129. Apotex, Inc. submitted ANDA No. 210299 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer

for sale of its proposed generic Diclofenac capsules 18 mg and 35 mg throughout the United States. By submitting this application, Apotex, Inc. has committed an act of infringement of the '095 patent under 35 U.S.C. § 271(e)(2)(A).

130. On information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 210299. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 210299 constitutes an act of infringement of the '095 patent under 35 U.S.C. § 271(e)(2)(A).

131. On information and belief, Apotex will include within the packaging of its generic Diclofenac capsules 18 mg and 35 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in the '095 patent.

132. On information and belief, a patient's use of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg according to the instructions included in the label and/or instructions for use of those products will constitute an act of direct infringement of one or more of the methods claimed in the '095 patent.

133. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg are a material part of one or more of the methods claimed in the '095 patent.

134. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg have no substantial uses that do not constitute infringement of one or more of the methods claimed in the '095 patent.

135. On information and belief, Apotex became aware of the '095 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using the approved formulation of ZORVOLEX®.

136. On information and belief, upon awareness of the '095 patent, Apotex either actually knew of the potential for infringement of one or more claims of the '095 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to perform one or more methods claimed in the '095 patent.

137. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration will constitute an act of contributory infringement and/or active inducement of infringement of the '095 patent.

138. On information and belief, Apotex knew or should have known that its commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg will actively induce the actual infringement of the '095 patent.

139. On information and belief, Apotex knew or should have known that its proposed generic Diclofenac capsules 18 mg and 35 mg will be especially made or especially adapted for use in an infringement of the '095 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg will actively contribute to the actual infringement of the '095 patent.

140. The commercial manufacture, distribution, marketing, use, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

141. Unless and until Apotex is enjoined from infringing the '095 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.



**COUNT X**

***(Declaratory Judgment of Infringement of the '095 Patent Under 35 U.S.C. § 271(b) and/or 271(c) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

142. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

143. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

144. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

145. On information and belief, Apotex will engage in the commercial manufacture, distribution, use, offer for sale, sale and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg immediately and imminently upon approval of ANDA No. 210299.

146. Apotex's actions, including but not limited to, the development of its proposed generic Diclofenac capsules 18 mg and 35 mg, filing of an ANDA with Paragraph IV certifications, and, on information and belief, the manufacture of exhibit batches of its proposed generic Diclofenac capsules 18 mg and 35 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

147. On information and belief, Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, distribute, sell, offer to sell, and/or import Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

148. On information and belief, Apotex will include within the packaging of its generic Diclofenac capsules 18 mg and 35 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in the '095 patent.

149. On information and belief, a patient's use of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg according to the instructions included in the label and/or instructions for use of those products will constitute an act of direct infringement of one or more of the methods claimed in the '095 patent.

150. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg are a material part of one or more of the methods claimed in the '095 patent.

151. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg have no substantial uses that do not constitute infringement of one or more of the methods claimed in the '095 patent.

152. On information and belief, Apotex became aware of the '095 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using the approved formulation of ZORVOLEX®.

153. On information and belief, upon awareness of the '095 patent, Apotex either actually knew of the potential for infringement of one or more claims of the '095 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to perform one or more methods claimed in the '095 patent.

154. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration will constitute an act of contributory infringement and/or active inducement of infringement of the '095 patent.

155. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

156. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration by Apotex will constitute contributory infringement and/or active inducement of infringement of the '095 patent.

157. Unless and until Apotex is enjoined from infringing the '095 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

### **COUNT XI**

#### ***(Infringement of the '096 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

158. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

159. Apotex, Inc. submitted ANDA No. 210299 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Diclofenac capsules 18 mg and 35 mg throughout the United States. By submitting this application, Apotex, Inc. has committed an act of infringement of the '096 patent under 35 U.S.C. § 271(e)(2)(A).

160. On information and belief, Apotex, Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 210299. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 210299 constitutes an act of infringement of the '096 patent under 35 U.S.C. § 271(e)(2)(A).

161. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of direct infringement of the '096 patent.

162. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

163. Unless and until Apotex is enjoined from infringing the '096 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

## **COUNT XII**

### ***(Declaratory Judgment of Infringement of the '096 Patent Under 35 U.S.C. § 271(a) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

164. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

165. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

166. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

167. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg immediately and imminently upon approval of ANDA No. 210299.

168. Apotex's actions, including but not limited to, the development of its proposed generic Diclofenac capsules 18 mg and 35 mg, the filing of an ANDA with Paragraph IV certifications, and, on information and belief, the manufacture of exhibit batches of its proposed generic Diclofenac capsules 18 mg and 35 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

169. On information and belief, Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

170. Any commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg prior to patent expiry will constitute direct infringement of the '096 patent.

171. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

172. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration by Apotex will constitute direct infringement of the '096 patent.

173. Unless and until Apotex is enjoined from infringing the '096 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

### **COUNT XIII**

#### ***(Infringement of the '328 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

174. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

175. Apotex, Inc. submitted ANDA No. 210299 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Diclofenac capsules 18 mg and 35 mg throughout the United States. By submitting this application, Apotex, Inc. has committed an act of infringement of the '328 patent under 35 U.S.C. § 271(e)(2)(A).

176. On information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 210299. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 210299 constitutes an act of infringement of the '328 patent under 35 U.S.C. § 271(e)(2)(A).

177. On information and belief, Apotex will include within the packaging of its generic Diclofenac capsules 18 mg and 35 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in the '328 patent.

178. On information and belief, a patient's use of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg according to the instructions included in the label and/or instructions for use of those products will constitute an act of direct infringement of one or more of the methods claimed in the '328 patent.

179. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg are a material part of one or more of the methods claimed in the '328 patent.

180. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg have no substantial uses that do not constitute infringement of one or more of the methods claimed in the '328 patent.

181. On information and belief, Apotex became aware of the '328 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using the approved formulation of ZORVOLEX®.

182. On information and belief, upon awareness of the '328 patent, Apotex either actually knew of the potential for infringement of one or more claims of the '328 patent, or was

willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to perform one or more methods claimed in the '328 patent.

183. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration will constitute an act of contributory infringement and/or active inducement of infringement of the '328 patent.

184. On information and belief, Apotex knew or should have known that its commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg will actively induce the actual infringement of the '328 patent.

185. On information and belief, Apotex knew or should have known that its proposed generic Diclofenac capsules 18 mg and 35 mg will be especially made or especially adapted for use in an infringement of the '328 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg will actively contribute to the actual infringement of the '328 patent.

186. The commercial manufacture, distribution, marketing, use, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

187. Unless and until Apotex is enjoined from infringing the '328 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

#### **COUNT XIV**

***(Declaratory Judgment of Infringement of the '328 Patent Under 35 U.S.C. § 271(b) and/or 271(c) by Apotex's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)***

188. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

189. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

190. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

191. On information and belief, Apotex will engage in the commercial manufacture, distribution, use, offer for sale, sale and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg immediately and imminently upon approval of ANDA No. 210299.

192. Apotex's actions, including but not limited to, the development of its proposed generic Diclofenac capsules 18 mg and 35 mg, filing of an ANDA with Paragraph IV certifications, and, on information and belief, the manufacture of exhibit batches of its proposed generic Diclofenac capsules 18 mg and 35 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

193. On information and belief, Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, distribute, sell, offer to sell, and/or import Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg.

194. On information and belief, Apotex will include within the packaging of its generic Diclofenac capsules 18 mg and 35 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in the '328 patent.

195. On information and belief, a patient's use of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg according to the instructions included in the label and/or instructions



for use of those products will constitute an act of direct infringement of one or more of the methods claimed in the '328 patent.

196. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg are a material part of one or more of the methods claimed in the '328 patent.

197. Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg have no substantial uses that do not constitute infringement of one or more of the methods claimed in the '328 patent.

198. On information and belief, Apotex became aware of the '328 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using the approved formulation of ZORVOLEX®.

199. On information and belief, upon awareness of the '328 patent, Apotex either actually knew of the potential for infringement of one or more claims of the '328 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to perform one or more methods claimed in the '328 patent.

200. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration will constitute an act of contributory infringement and/or active inducement of infringement of the '328 patent.

201. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

202. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, distribution, marketing, offer for sale, sale, and/or importation of Apotex's

proposed generic Diclofenac capsules 18 mg and 35 mg before patent expiration by Apotex will constitute contributory infringement and/or active inducement of infringement of the '328 patent.

203. Unless and until Apotex is enjoined from infringing the '328 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

### **JURY TRIAL DEMAND**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby request a trial by jury of all issues so triable.

### **PRAYER FOR RELIEF**

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Apotex has infringed the '544, '387, '721, '854, '095, '096, and '328 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210299 under section 505(j) of the FDCA, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of infringement of the '544, '387, '721, '854, '095, '096, and '328 patents;

b. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Apotex's ANDA No. 210299 shall be a date which is not earlier than the expiration date of the '544, '387, '721, '854, '095, '096, and '328 patents, as extended by any applicable period of exclusivity;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its

behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '544, '387, '721, '854, '095, '096, and '328 patents;

d. If Apotex engages in the commercial manufacture, use, offer to sell, sale, or importation of Apotex's generic product disclosed in its ANDA No. 210299 prior to the expiration of the '544, '387, '721, '854, '095, '096, and '328 patents, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

e. If Apotex engages in the commercial manufacture, use, offer to sell, sale, or importation of Apotex's generic product disclosed in its ANDA No. 210299 prior to the expiration of the '544, '387, '721, '854, '095, '096, and '328 patents, as extended by any applicable period of exclusivity, judgment awarding Plaintiffs damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C);

f. That a declaration be issued under 28 U.S.C. § 2201 that if Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Diclofenac capsules 18 mg and 35 mg prior to patent expiration, it will constitute an act of infringement of the '544, '387, '721, '854, '095, '096, and '328 patents;

g. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

h. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

i. That this Court award such other and further relief as It may deem just and proper.

Dated: October 31, 2017

FISH & RICHARDSON P.C.

By: /s/ Martina Tyreus Hufnal

Martina Tyreus Hufnal (#4771)  
222 Delaware Avenue, 17<sup>th</sup> Floor  
P. O. Box 1114  
Wilmington, DE 19899-1114  
Phone: 302-652-5070 / Fax: 302-652-0607  
Emails: tyreus-hufnal@fr.com

W. Chad Shear (#5711)  
Megan A. Chacon  
12390 El Camino Real  
San Diego, CA 92130  
Phone: 858-678-5070 / Fax: 858-678-5099  
Email: shear@fr.com; chacon@fr.com

*Attorneys for Plaintiffs ICEUTICA PTY LTD and IROKO  
PHARMACEUTICALS, LLC*